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10/554,703	10/09/2006	Susanne Lang-Fugmann	9741-014-999	9359

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EXAMINER	
KASSA, TIGABU	
ART UNIT	PAPER NUMBER
1619	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,703	LANG-FUGMANN, SUSANNE	
	Examiner	Art Unit	
	TIGABU KASSA	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/31/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the amendment filed December 31, 2008. **Claims 1-13 are currently pending. Claims 1-13 are under consideration in the instant office action.**

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 12/31/08 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the references.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-2, 7-9, and 11-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ippen et al. (US Patent No. 4,956,370) as evidenced by (http://www.thefreedictionary.com/polyethylene+glycol) is maintained.

Instant claims 1 and 2 recite a pharmaceutical, antimycotically active nail lacquer for the treatment or prophylaxis of fungal infections of nails and skin comprising an optionally substituted 2-aminothiazole. Instant claims 7-9 recite pharmaceutical, antimycotically active nail lacquer also comprises a plasticizer, and at least one solvent from the list recited in instant claim

9, respectively. Instant claim 11 recites that the antimycotically active ingredient in the composition is Abafungin. Instant claims 12 and 13 recite a method for the treatment and prophylaxis of fungal infections respectively.

Ippen et al. disclose a pharmaceutical composition useful for combating mycoses comprising substituted 2-aminothiazole and other pharmaceutical excipients (column 1, lines 20-68, column 2, lines 1-21, column 146, line 46-49, and see Abstract). Ippen et al. disclose that the pharmaceutical preparation could be in the form of tablets, coated tablets, capsules, pills, granules, suppositories, solutions, suspensions, emulsions, pastes, ointments, gels, creams, lotions, powders, or sprays (column 19, lines 62-66). It is examiner's position that the pharmaceutical composition described by Ippen et al. as being able to be prepared in various forms, are capable of being nail lacquer compositions. As a result Ippen et al. anticipates instant claims 1 and 2.

Ippen et al. disclose the pharmaceutical composition also comprises a plasticizer such as polyethylene glycols (column 20, line 30) which are known plasticizers in the art and also see (http://www.thefreedictionary.com/polyethylene+glycol, checked June 24, 2008), solvents like water, ethyl alcohol, isopropyl alcohol, ethyl acetate etc (column 20, lines 48-51), which reads on instant claims 7-9.

Ippen et al. also disclose, in the examples section, the use of Abafungin (Table A column 141, compound 149) in *in vitro* activity test, which is the structure of Abafungin, which reads on instant claim 11.

Ippen et al. teach that the pharmaceutical composition can be used for the treatment, prevention, amelioration and/or cure of mycoses (column 21, lines 26-27) either

dermatomycoses and systemic mycoses (column 19, lines 32-33) (which includes nails). Specifically, Ippen et al. disclose a method of combating mycoses through administering the above disclosed pharmaceutical composition (column 146, lines 54-58), which reads on claims 12-13.

Response to Arguments

Applicant's claim amendments and arguments filed 12/31/08 have been fully considered but they are not persuasive. Thus, the instant rejection is deemed to remain **proper and is maintained.**

Applicant has asserted that Ippen et al. does not anticipate the above recited claims, because Ippen et al. does not disclose each and every feature recited in the claims. Applicant's argument hinges on the assertion that even though Ippen et al. disclose a large number of various types of pharmaceutical formulations namely of tablets, coated tablets, capsules, pills, granules, suppositories, solutions, suspensions, emulsions, pastes, ointments, gels, creams, lotions, powders, or sprays (column 19, lines 62-66), Ippen et al. is silent as to a "pharmaceutical, antimycotically active nail lacquer". The examiner respectfully disagrees with applicant's assertion, because as written, for example, independent claim 1 requires a pharmaceutical formulation comprising an optionally substituted 2-aminothiazole of formula (I). The claim does not recite the incorporation of other agents that can construe the instantly claimed invention to a nail lacquer. Furthermore, the examiner applied the correct legal standards while weighing whether to give weight to the intended use recited in the preamble or not, as set forth in the MPEP by reading the preamble in the context of the entire claim.

Applicant is reminded that a claim preamble has the import that the claim as a whole suggests for it, if the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to **give life, meaning, and vitality' to the claim**. However, in the instant case the intended use recited in the preamble of the claims does not give any life, meaning, or vitality to the claim as it only contains an optionally substituted 2-aminothiazole of formula (I). Furthermore, a **preamble** is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Applicant has not demonstrated how their product is patentably distinct from the cited prior art nor do the claims as currently written distinguish the instant invention over the prior art.

Additionally, the prior art reference should be viewed as a whole; it is not necessary to restrict the analysis of the prior art to a single embodiment as long as the skilled artisan is able to envisage to select the claimed formulation form from the various possible permutations. The choice delineated in applicant's remarks are between 16 possible permutations disclosed, wherein one form can be clearly envisaged by one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

The rejection of claims 1, 2, 3, 5-6 and 10 under 35 U.S.C. 103(a) as being unpatentable over Ippen et al. (US Patent No. 4,956,370) as evidenced by (http://www.thefreedictionary.com/polyethylene+glycol, checked June 24, 2008) in view of Samour et al. (US Patent No. 6,224,887, Issued on May 1, 2001) is maintained.

Applicant Claims

The claimed subject matter of instant claims 1-2 is set forth above. Additionally, applicant claims in instant claims 3, 5, and 6 the pharmaceutical antimycotically active nail lacquer comprises permeation enhancer and polymeric film-forming agent and the film-forming agent being belonging to the group of water-insoluble acrylate polymers or methacrylate polymers and comprises a copolymer that belongs to the compound class of alkylvinylethers, maleic acid anhydride, alkylated poly(vinylpyrrolidones) and ammonium methacrylates, respectively. Instant claim 10 recites the different % by weight amounts of various components of the pharmaceutical, antimycotically active nail lacquer.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Ippen et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Ippen et al. do not teach the incorporation of permeation enhancer as recited in instant claim 3 and the film forming agents as recited in instant claims 5-6. Ippen et al. also do not teach the incorporation of the other ingredients and the amounts in the composition as recited in instant claim 10. These deficiencies are cured by the teachings of Samour et al.

Samour et al. teach an antifungal nail lacquer comprising permeation (penetration) enhancing agent (column 3, lines19-21) and polymeric film-forming agent (column 3, line 23). For the types of film forming agents Samour et al. also teach that film forming agents can

include acrylate (co)polymers, methacrylate (co)polymers, and copolymers of alkyl vinyl ether and maleic anhydride (column 6, line 38-40)

Samour et al. (US Patent No. 6,224,887) teach an antifungal nail lacquer comprising 5-20 % of an antifungal active agent, (column 12, line 25-26), 0.5-35 % enhancer (column 5, line 26), 20-40 % film forming polymer (column 8, line 43), 53% ethanol (column 16, line 55-56), and 2-10% plasticizer (column 9, line 23).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Ippen et al. through incorporating permeation enhancing agent and polymeric film-forming agents, because Samour et al. teach the incorporation of such agents in nail lacquer compositions. The skilled artisan would have been motivated to incorporate permeation enhancers, because as it is conventionally known agent the permeation enhancer helps for the penetration of various pharmaceutical actives in a targeted part of the body. Additionally, film forming polymers are incorporated as a conventional agent for forming films. The skilled artisan would have had a reasonable expectation of success in combining the teachings, because Ippen et al. teach that the pharmaceutical composition can be used for the treatment prevention, amelioration and/or cure of mycoses (column 21, lines 26-27) either dermatomycoses and systemic mycoses (column 19, lines 32-33), which includes nails and also Samour et al. teach a nail lacquer composition.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Ippen et al. (US Patent No. 4,956,370) as applied to claims 1, 2, 3, 5-6, and 10 above, and further in view of Samour et al. (US Patent No. 6,224,887) and Wohlrab et al. (US Patent No. 6,719,986) is maintained.

Applicant Claims

The claimed subject matter of instant claims 1-3 is set forth above. Instant claim 4 requires hyaluronate lyase as permeation enhancer agent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Ippen et al. and Samour et al. are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Ippen et al. and Samour et al. do not teach in the incorporation of hyaluronate lyase as the permeation enhancing agent. This deficiency is cured by the teaching of Wohlrab et al..

Wohlrab et al. teach hyaluronate lyase as a penetration enhancing agent in topical agents (see Abstract).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Ippen et al. and Samour et al. by

incorporating hyaluronate lyase, because Wohlrab et al. teach the use of hyaluronate lyase as permeation enhancing agent in topical agents. The skilled artisan would have been motivated to incorporate the permeation enhancer hyaluronate lyase, because Wohlrab et al. teach that it has been known for a long time that through the presence of one or more special auxiliary substances such as hyaluronate lyase the penetration of active agents can be made easier and modulated (column 1, lines 32-35). The skilled artisan would have had a reasonable expectation of success in combining the prior art teachings, because all the three references teach the delivery of agents topically.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's claim amendments and arguments filed 12/31/08 have been fully considered but they are not persuasive. Thus, all of the rejections under 35 U.S.C. 103(a) are deemed to remain **proper and are maintained.** Applicant has argued in combination for all the rejections made under 35 U.S.C. 103(a), therefore, the examiner also addresses them together as follows:

Applicant has asserted that Ippen et al. does not anticipate claims 1-2, because Ippen et al. does not disclose each and every feature recited in the claims. Applicant's argument hinges on the assertion that even though Ippen et al. disclose various forms of administration of the formulation such as locally, orally, parenterally, etc, Ippen et al. is silent as to a "pharmaceutical, antimycotically active nail lacquer". The examiner strenuously but respectfully disagrees with

applicant's assertion, because as written for example independent claims 1-2 require a pharmaceutical formulation comprising an optionally substituted 2-aminothiazole of formula (I). The claim does not recite the incorporation of other agents that can construe the instantly claimed invention to a nail lacquer. Furthermore, the examiner applied the correct legal standards while weighing whether to give weight to the intended use recited in the preamble or not, as set forth in the MPEP by reading the preamble in the context of the entire claim.

Applicant is reminded that a claim preamble has the import that the claim as a whole suggests for it, if the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to **give life, meaning, and vitality' to the claim**. However, in the instant case the intended use recited in the preamble of the claims does not give any life, meaning, or vitality to the claim as it only contains an optionally substituted 2-aminothiazole of formula (I). Furthermore, a **preamble** is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Applicant has not demonstrated how their product is patentably distinct from the cited prior art nor do the claims as currently written distinguish the instant invention over the prior art. With regard to the possible forms of administration disclosed by Ippen et al. one of the forms is "locally". According to the instantly claimed invention the formulation is intended to be applied to the nail. One of ordinary skill in that art can infer from

such intended use the formulation is going to be locally applied to the nail. Hence, Ippen et al. clearly anticipates each limitation of instant claims 1-2.

Additionally, applicant also asserts that the examiner did not provide reason to combine the prior art teachings and did not demonstrate whether a person skilled in the art would have had a reasonable expectation of success. This assertion is completely unfounded, because the examiner has provided both in the previous office action and also in the instant office action as described above sufficient reason why one of ordinary skill in the art would be motivated to incorporate the recited agents in the formulation and also why one of ordinary skill in the art would have had a reasonable expectation of success. Applicant also argues that the composition disclosed by Ippen et al. are preferably administered parenterally, in particular intravenously, therefore, one of ordinary skill in the art would not have had reasonably expected the composition of Ippen et al in the form of a pharmaceutical, antimycotically active nail lacquer. The examiner reminds applicant the references should be considered as a whole not in pieces. Ippen et al. even though in preferred embodiment disclose parenteral, in particular intravenous administration, as it is discussed above Ippen et al. also disclose the pharmaceutical formulation may be administered locally (column 21, line 30), for the sake of argument which is a sufficient teaching for one of ordinary skill in the art to clearly envisage with sufficient specificity a nail laquer. Furthermore, Ippen et al. disclose that the pharmaceutical composition can be used for the treatment prevention, amelioration and/or cure of mycoses (column 21, lines 26-27) either dermatomycoses or systemic mycoses (column 19, lines 32-33), which includes nails. Moreover, the clear disclosure of instant invention by Ippen et al. constitutes a rational to combine Samour et al, which teach an antifungal nail lacquer comprising an antifungal agent and the other

ingredients recited in the instant claims such as a permeation enhancer, which is also disclosed by Wohlrab et al. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Claims 1-13 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa 3/13/09

/Mina Haghighatian/
Primary Examiner, Art Unit 1616